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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,228	12/03/2001	Karen M. Lyons	22058-554	7961

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EXAMINER

MARVICH, MARIA

ART UNIT	PAPER NUMBER
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1636

10

DATE MAILED: 11/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Appli ation No.

10/005,228

Applicant(s)

LYONS ET AL.

Examiner

Maria B Marvich, PhD

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-- The MAILING DATE of this communication appears on th cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-38 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-27 and 32, drawn to a method for reducing the severity of a bone fracture comprising inhibition of the activity or expression of BMP-3 polypeptide, classified in class 514, subclass 44.
 - II. Claims 28, 29 and 33, drawn to a method of preventing unwanted bone growth comprising increasing the activity of BMP-3 polypeptide with a nucleic acid, classified in class 514, subclass 44.
 - III. Claims 28, 30, 31 and 33, drawn to a method of preventing unwanted bone growth comprising increasing the activity of BMP-3 polypeptide with a polypeptide, classified in class 514, subclass 2.
 - IV. Claim 34, drawn to a method for identifying a promoter of bone growth comprising contacting BMP-3 polypeptide with a test compound, classified in class 435, subclass 2.
 - V. Claim 35-38, drawn to a method for identifying a promoter of bone growth comprising contacting BMP-3 nucleic acid with a test compound, classified in class 435, subclass 6.

The inventions are distinct each from the other because of the following reasons:

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The methods of Group I-V are biologically and functionally different and distinct from each other and thus one does not render the other obvious. The method of Group I comprises steps, which are not required for or are not present in the methods of Group II-V: the method of Group I involves the additional steps of assaying for bone fracture severity which is not required of any of Groups II-V. The methods of Group II comprise steps, of which are not required for nor are present in the methods of Group I or III-V: the method of Group II involves the additional steps of preparing and administration to a subject an inductive nucleic acid for an increase of BMP-3. The methods of Group III comprise steps, of which are not required for or are not present in the methods of Group I-II or IV-V: the method of Group III involves the additional steps of preparing and administration to a subject an inductive protein for an increase of BMP-3. The methods of Group IV comprise steps, of which are not required for or are not present in the methods of Group I-III or V: the method of Group IV involves the additional steps of contacting BMP-3 protein with a test compound and detection of binding between BMP-3 protein and the test compound. The methods of Group V comprise steps, of which are not required for or are not present in the methods of Group I-IV: the method of Group V involves the additional steps of contacting BMP-3 nucleic acid with a test compound and detection of binding between BMP-3 nucleic acid and the test compound. Furthermore, the assays of Group IV and V can be performed *in vitro* whereas the methods of Group I-III are performed *in vivo*. The outcomes of each of the methods are different and distinct from one another. The method of Group I results in reduction of bone fractures which is an opposite and non-overlapping effect of the methods of Group II-III which results in decreased bone growth. The method of Group II result in identification of a nucleic acid that increases BMP-3 polypeptide while the method of

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Group III in identification of a protein that increases BMP-3 polypeptide. The method of Group IV identifies an inhibitor BMP-3 protein function while that of Group V identifies an inhibitor BMP-3 nucleic acid. Therefore, the inventions are capable of supporting separate patents.

The searches required for the different groups are not coextensive; a search for art pertaining to methods of reducing bone fractures is not coextensive with a search for art pertaining to methods of decreased bone growth. Therefore, restriction for examination purposes as indicated is proper.

These inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification Group I and II (514/44) vs. Group III (514/2) vs. Group IV (Class 435/4) vs. Group V (435/6) and their recognized divergent subject matter.

Applicant is reminded that upon cancellation of claims to a non-elected inventions, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B Marvich, PhD whose telephone number is (703) 605-1207. The examiner can normally be reached on M-F (6:30-3:00).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, PhD can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to receptionist, whose telephone number is (703) 308-0196.

Maria B Marvich, PhD
Examiner
Art Unit 1636

MM
October 24, 2003


GERRY LEFFERS
PRIMARY EXAMINER